

PATENT COOPERATION TREATY

PCT

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PI 0206903-2	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/BR 2003/000202	International filing date (<i>day/month/year</i>) 22 December 2003 (22.12.2003)	Priority Date (<i>day/month/year</i>) 20 December 2002 (20.12.2002)
International Patent Classification (IPC) or national classification and IPC IPC⁷: C12Q 1/68, G01N 33/50		
Applicant UNIVERSIDADE FEDERAL DE SAO PAULO - UNIFESP		

1.	This international preliminary examination report has been prepared by this International Preliminary Examination Authority and is transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of <u> 4 </u> sheets, including this cover sheet. <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of _____ sheets.
3.	This report contains indications relating to the following items: I. <input checked="" type="checkbox"/> Basis of the opinion II. <input type="checkbox"/> Priority III. <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV. <input type="checkbox"/> Lack of unity of invention V. <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI. <input type="checkbox"/> Certain documents cited VII. <input type="checkbox"/> Certain defects in the international application VIII. <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand 14.07.2004	Date of completion of this report 6 May 2005 (06.05.2005)
Name and mailing address of the IPEA/AT Austrian Patent Office Dresdner Straße 87 A-1200 Vienna Facsimile No. 1/53424/200	Authorized officer MOSSER R. Telephone No. 1/53424/437

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International application No.

PCT/BR 2003/000202

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____.
- ☐ the claims:
 pages _____, as originally filed
 pages _____, as amended (together with any statement) under Article 19
 pages _____, filed with the demand
 pages _____, filed with the letter of _____.
- ☐ the drawings:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____.
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____.
- ☐ the claims, Nos. _____.
- ☐ the drawings, sheets/fig _____.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as „originally filed“ and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 17,18.

because:

☒ the said international application, or the said claims Nos. 17,18 relate to the following subject matter which does not require an international preliminary examination (*specify*):

Remark: Although claims 17 and 18 relate to a method of diagnosis practiced on the human or animal body (see PCT Rule 39.1(iv)) the examination was carried out and based on the alleged effects.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

I. Statement			
Novelty (N)	Claims	1-22	YES
	Claims	----	NO
Inventive step (IS)	Claims	1-22	YES
	Claims	----	NO
Industrial applicability (IA)	Claims	1-16, 19-22	YES
	Claims	17, 18	NO

Citations and explanations (Rule 70.7)

The following document has been cited in the Search Report:

D1: HATTORI, M.A. et al. Angiotensin I-Converting Enzyme Isoforms (High and Low Molecular Weight) in Urine of Premature and Full-Term Infants. Hypertension, 2000, Vol. 35, No. 6, pages 1284-1290

D1 is an example which demonstrates that identification of angiotensin I-converting enzyme (ACE) in urine in e.g. hypertensive patients is a well established method. However, D1 does not suggest the testing of the isoforms (polypeptides and genes thereof) which are given in present claims. Therefore, novelty and inventive step are recognized for the subject-matters of claims 1-22.

It is clear that ACE is usually detected outside of the human body e.g. in urine. Claims 17 and 18 comprise "the detection in individuals". That expression could mean that a method is practised on the human body – whereas it seems to be clear that the detection in urine is done outside of the human body (claim 19). In other words claims 17 and 18 inter alia relate to methods of diagnosis practiced on the human or animal body (see PCT Rule 39.1(iv)). The subject-matters of these claims are not industrially applicable. Industrial applicability is given for the subject-matters of claims 1-16 and 19-22.